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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,935	08/08/2001	Stuart D. Edwards	9222.16785-CON	5246

26308 7590 04/07/2005

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,935

Applicant(s)

EDWARDS, STUART D.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 107-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 107-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 25, 2005 has been entered.

Specification

The disclosure is objected to because of the following informalities: the "Cross-Related Applications" paragraph should be amended to reflect the most current status (i.e. US Patent Number or "abandoned") for each related application.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 107-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (5,823,197).

As shown in Figure 3C, Edwards provides a device comprising an expandable structure (balloon 132) and a plurality of electrodes (135) carried by the expandable structure and deployable into tissue. The examiner maintains that the Edwards device

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is inherently capable of treating a sphincter, and that the electrodes are inherently capable of operating in a first state to detect tissue and a second state to treat tissue. It is noted that the claims do not positively recite the generator or ESU connected to the electrodes enabling the electrodes to operate in each of the recited states.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-88 of U.S. Patent No. 6,056,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide

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mapping of sphincter tissue. To have used the '744 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,254,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '598 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,258,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal

pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '087 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,402,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '744 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-52 of U.S. Patent No.

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6,077,257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '257 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No.

6,673,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '070 claimed device to provide mapping

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and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,613,047. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '047 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-90 of U.S. Patent No. 6,749,607. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal

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pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '607 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

Claims 107-113 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/911,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the teachings of Imran (5,156,151) and Karlstrom et al ("Ectopic jejunal pacemakers...intestinal pacing", 1989). The Imran reference teaches that it is generally known to provide an expandable device with electrodes that are used to perform both mapping and treatment functions. Karlstrom et al teach that it is known to provide mapping of sphincter tissue. To have used the '874 claimed device to provide mapping and ablation functions would have been an obvious consideration in view of the Imran and Karlstrom et al teachings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant has amended the claim for priority to remove the Edwards et al reference as prior art. It is noted that applicant's petition to amend the priority has been granted. The examiner has now modified the obvious double patenting rejection to use alternative prior art references to teach the mapping and ablation of tissue. It is noted that the Karlstrom et al article was cited by the applicant in an Information Disclosure Statement.

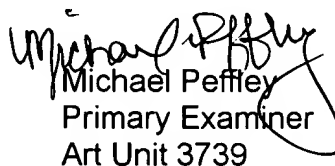
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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April 4, 2005